University of New Mexico Comprehensive Cancer Center/New Mexico Cancer Care Alliance

STANDARD OPERATING PROCEDURE

Clinical Research Office

Title: EMERGENCY USE OF AN UNAPPROVED INVESTIGATIONAL DRUG OR AGENT

SOP No.: 4.9	Version No.: 3	Effective Date: August 2009

Owner: NMCCA Medical Director

Name: Olivier Rixe, MD, PhD

Signature _____ Date 3/28/2018

Authorized / Approved by:

Name: Olivier Rixe, MD, PhD

Title: NMCCA Medical Director

Signature _____ Date 3/28/2018

INTRODUCTION AND PURPOSE

Emergency use of an unapproved drug or biologic is intended to benefit a single patient who is not eligible for an approved research study opened by the University of New Mexico Comprehensive Cancer Center (UNMCCC) and/or New Mexico Cancer Care Alliance (NMCCA). Generally, emergency use of a test article requires an IND. The FDA regulations, 21 CRF 56.104(c), provide an "emergency use" exemption from rules requiring prior IRB review and approval. However, reporting the use to the IRB is required by the FDA. UNMCCC requires consultation with the IRB prior to use if possible.

This SOP aims to support physicians by clarifying the strict emergency use requirements, and by outlining the necessary procedures, to help ensure physicians are in full compliance with those requirements.

The following five (5) criteria must be met to comply with federal regulations.

1. The test article is used one time per institution to treat a single patient, and
2. The patient has a condition that is life-threatening or severely debilitating, and
3. No standard treatment is available, and
4. There is not sufficient time to obtain IRB review and approval, and
5. The emergency use is reported to the appropriate IRB within five (5) working days; when possible, the treating physician should consult with the appropriate IRB prior to use.

This SOP provides a checklist guide to assure compliance to each step of the process (SOP 4.9 Form A).

Please note: Emergency use is emergency clinical care and does not meet the definition of research, 45 CFR 46.102(d), although the FDA considers it research but allows an exemption from the appropriate IRB review.

SCOPE

This SOP applies to all study research personnel including faculty, staff, student and or others who are involved in human subject's research that fall under the jurisdiction of the UNMCCC Clinical Research Office and NMCCA.

APPLICABLE REGULATIONS AND GUIDELINES

21 CRF 56.104(c)	Exemptions from IRB Requirement
21 CFR 312.60	General responsibilities of investigators
21 CFR 312.62	Investigator recordkeeping and record retention
21 CFR 312.64	Investigator reports
45 CFR 46.102(d)	Definitions
HRP-322 WORKSHEET: Emergency Use	http://hsc.unm.edu/som/research/hrrc/irblibrary.shtml
HRRC Emergency Use Notification	HRPO electronic CLICK submission: Reportable New Information http://hsc.unm.edu/som/research/hrrc/irblibrary.shtml

FDA Information Sheets, 8/30/2011	Emergency Use of an Investigational Drug or Biologic - Information Sheet http://www.fda.gov/RegulatoryInformation/Guidances/ucm126491.htm
Physician Request for a Single Patient IND for Compassionate or Emergency Use	http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm107434.htm
HRRC 9.1 & 9.2 Emergency Use	http://hsc.unm.edu/som/research/hrrc/docs/HRRC_Manual.pdf

REFERENCES TO OTHER APPLICABLE SOPs

N/A

RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in research protocols.

UNMCCC CRO Medical Director

NMCCA Medical Director

Director UNMCCC CRO, Executive Director NMCCA

Principal Investigator

Sub Investigator

Clinical Research Coordinator

Clinical Research Nurse

NMCCA Clinical Research Supervisor

UNMCCC Clinical Research Operations Manager

NMCCA Clinical Research Manager

Study Pharmacist

PROCEDURES

Assessing and evaluating the patient

Owner	Criteria/Steps
Director UNM CCC CRO and NMCCA Medical Director	Review the following five (5) FDA requirements 1. The test article is used one time per institution to treat a single patient, and 2. The patient has a condition that is life-threatening or severely debilitating, and 3. No standard treatment is available, and 4. There is not sufficient time to obtain IRB review and approval, and

PI/Sub I	5. The emergency use is reported to the appropriate IRB within five (5) working days; when possible, the treating physician should consult with the appropriate IRB prior to use. Assure that each requirement is met or can be met. Document in the patient medical record that each criterion can be met or will be met with appropriate explanation. Assure source documentation is available and in the patient medical record to support the criteria when appropriate.

Implementing use of the drug

Owner	Criteria/Steps
Director UNM CCC CRO and NMCCA Medical Director PI/Sub I NMCCA Clinical Research Supervisor UNM CCC Clinical Research Operations Manager NMCCA Clinical Research Manager Study Pharmacist	Access and review the HRPO HRP-322 Worksheet: Emergency Use http://hsc.unm.edu/som/research/hrrc/irblibrary.shtml (SOP 4.9 Form A) Access and review the HRRC Reportable New Information form for electronic submission in CLICK If possible contact the HRRC at (505) 272-1129 prior to the procedure. Follow instructions by the HRRC and as required by SOP 4.9 Forms A, B. If it is not possible to contact the HRRC prior to the emergency use, Contact the HRRC ASAP after treatment. Verify what forms and information may be required from the checklist (SOP 4.9 Form A).

Obtaining Informed Consent

Owner	Criteria / Steps
Director UNM CCC CRO and NMCCA Medical Director PI/Sub I	Obtain written consent by the patient or the patient's legally authorized representative. If the patient meets any of the following conditions, informed consent may be waivered. 1. The patient is confronted with a life threatening situation

Research/ Regulatory/ Data Coordinator NMCCA Clinical Research Supervisor UNM CCC Clinical Research Operations Manager NMCCA Clinical Research Manager Study Pharmacist	2. The physician cannot communicate with the patient 3. Time is not sufficient to obtain consent from the patient's legally authorized representative 4. No alternative method of approved or generally recognized therapy is available that provides equal or greater likelihood of saving the patient's life

Obtaining the drug and notifying the FDA

Owner	Criteria / Steps
Director UNM CC CR and NMCCA Medical Director Principal Investigator Research / Regulatory / Data Coordinator Regulatory Manager Nurse Manager Study Pharmacist	Contact the manufacturer to determine if the product can be made available under its IND. If not, or there is not time, telephone or fax communication with the FDA is required. Industry sponsored IND: notify the manufacturer or sponsor about the emergency use, (the sponsor notifies the FDA for IND approval). Physician sponsored IND, or if no IND exists; notify the FDA about the emergency use CDER Drugs; Division of Drug Information (HFD_240) 301-827-4570 CBER Biologics; Office of Communication, Training and Manufacturers Assistance (HFM-41) (800) 835-4709 or (301) 827-2000 industry.biologics@fda.gov After normal working hours, call FDA's Office of Emergency Operations at 301-796-8240.

Submitting a post use written report

Owner	Criteria / Steps
Director UNM CC CRO and NMCCA Medical Director Principal Investigator Research / Regulatory / Data Coordinator Regulatory Manager Nurse Manager Study Pharmacist	Within 5 working days; Have the decision to use the drug or device reviewed and evaluated in writing by a physician who did not participate in the emergency use and submit to ***only the HRRC.*** Provide a copy of any patient information provided to the Sponsor or company to ***only the HRRC.*** Complete a post use report (SOP 4.9 Form D) and include the following information; 1. Physician's name, department address, phone numbers 2. Name of test article (unapproved drug, biologic) dosage, route 3. Name of sponsor 4. Date of HRRC notification 5. Date test article used 6. Patient Name and MRN 7. Rationale for test article use 8. Results of test article use: if not available within the initial reporting period (5 working day), results must be reported to the HRRC within 10 working days of the treatment. 9. The IND number. 10. Copy of signed Informed Consent or justification to waive informed consent. Submit a copy of the post treatment report to; HRRC If the IND holder is the sponsor, submit to the Sponsor. If the investigator is the IND holder, submit to the FDA. Study regulatory binder. Clinical Research Supervisor NMCCA Medical Director Office of Quality Assurance